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the service or fails to timely refund excess collections.

(3) Fails to submit a claim on a standard form for services provided for which payment is made on a fee schedule basis.

(4) Imposes a charge for completing and submitting the standard claims form.

[66 FR 55332, Nov. 1, 2001]

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies

SOURCE: 66 FR 45176, Aug. 28, 2001, unless otherwise noted.

§ 414.100 Purpose.

This subpart implements fee schedules for PEN items and services as authorized by section 1842(s) of the Act.

§ 414.102 General payment rules.

(a) General rule. For items and services furnished on or after January 1, 2002, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of—

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with §§ 414.104.

(b) Payment classification. (1) CMS or the carrier determines fee schedules for Parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, as specified in § 414.104.

(2) CMS designates the specific items and services in each category through program instructions.

(c) Updating the fee schedule amounts. For each year subsequent to 2002, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding year.

§ 414.104 PEN Items and Services.

(a) Payment Rules. Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

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(b) Fee schedule amount. The fee schedule amount for payment for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

§ 414.200 Purpose.

This subpart implements sections 1834 (a) and (h) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment and prosthetic and orthotic devices for Medicare beneficiaries.

[57 FR 57689, Dec. 7, 1992]

§ 414.202 Definitions.

For purposes of this subpart, the following definitions apply:

Covered item update means the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) for the 12-month period ending with June of the previous year.

Durable medical equipment means equipment, furnished by a supplier or a home health agency that—

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose;

(3) Generally is not useful to an individual in the absence of an illness or injury; and

(4) Is appropriate for use in the home. (See § 410.38 of this chapter for a description of when an institution qualifies as a home.)

Prosthetic and orthotic devices means—

(1) Devices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies;

(2) One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; and

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition.

The following are neither prosthetic nor orthotic devices—

(1) Parenteral and enteral nutrients, supplies, and equipment;

(2) Intraocular lenses;

(3) Medical supplies such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are furnished by an HHA as part of home health services under §409.40(e) of this chapter;

(4) Dental prostheses.

Region means those carrier service areas administered by CMS regional offices.

[57 FR 57689, Dec. 7, 1992]

§414.210 General payment rules.

(a) *General rule.* For items furnished on or after January 1, 1989, except as provided in paragraphs (c) and (d) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§414.220 through 414.232.

(b) *Payment classification.* (1) The carrier determines fee schedules for the following classes of equipment and devices:

(i) Inexpensive or routinely purchased items, as specified in §414.220.

(ii) Items requiring frequent and substantial servicing, as specified in §414.222.

(iii) Certain customized items, as specified in §414.224.

(iv) Oxygen and oxygen equipment, as specified in §414.226.

(v) Prosthetic and orthotic devices, as specified in §414.228.

(vi) Other durable medical equipment (capped rental items), as specified in §414.229.

(vii) Transcutaneous electrical nerve stimulators (TENS), as specified in §414.232.

(2) CMS designates the items in each class of equipment or device through its program instructions.

(c) *Exception for certain HHAs.* Public HHAs and HHAs that furnish services or items free-of-charge or at nominal prices to a significant number of low-income patients, as defined in §413.13(a) of this chapter, are paid on the basis of 80 percent of the fee schedule amount determined in accordance with the provision of §§414.220 through 414.230.

(d) *Prohibition on special limits.* For items furnished on or after January 1, 1989 and before January 1, 1991, neither CMS nor a carrier may establish a special reasonable charge for items covered under this subpart on the basis of inherent reasonableness as described in §405.502(g) of this chapter.

(e) *Maintenance and servicing.* (1) *General rule.* Except as provided in paragraph (e)(2) of this section, the carrier pays the reasonable and necessary charges for maintenance and servicing of purchased equipment. Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Payment is made, as needed, in a lump sum based on the carrier's consideration of the item. Payment is not made for maintenance and servicing of a rented item other than the maintenance and servicing fee for other durable medical equipment, as described in §414.229(e).

(2) *Exception.* For items purchased on or after June 1, 1989, no payment is made under the provisions of paragraph (e)(1) of this section for the maintenance and servicing of:

(i) Items requiring frequent and substantial servicing, as defined in §414.222(a);

(ii) Capped rental items, as defined in §414.229(a), that are not purchased in accordance with §414.229(d); and

(iii) Oxygen equipment, as defined in §414.226.

(f) *Replacement of equipment.* Except as provided in §414.229(g), if a purchased item of DME or a prosthetic or orthotic device paid for under this subpart has been in continuous use by the patient for the equipment's reasonable

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useful lifetime or if the carrier determines that the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement equipment, payment is made on a purchase basis.

[57 FR 57689, Dec. 7, 1992]

§ 414.220 Inexpensive or routinely purchased items.

(a) *Definitions.* (1) *Inexpensive equipment* means equipment the average purchase price of which did not exceed \$150 during the period July 1986 through June 1987.

(2) *Routinely purchased equipment* means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

(3) *Accessories.* Effective January 1, 1994, accessories used in conjunction with a nebulizer, aspirator, or ventilator excluded from § 414.222 meet the definitions of “inexpensive equipment” and “routinely purchased equipment” in paragraphs (a)(1) and (a)(2) of this section, respectively.

(b) *Payment rules.* (1) Subject to the limitation in paragraph (b)(3) of this section, payment for inexpensive and routinely purchased items is made on a rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount.

(2) Effective January 1, 1994, payment for ostomy supplies, tracheostomy supplies, urologicals, and surgical dressings not furnished as incident to a physician's professional service or furnished by an HHA is made using the methodology for the inexpensive and routinely purchased class.

(3) The total amount of payments made for an item may not exceed the fee schedule amount recognized for the purchase of that item.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for payment of purchase or rental of inexpensive or routinely purchased items furnished in 1989 and 1990 is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for inexpensive or routinely purchased items that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item. A separate determination of an average reasonable charge is made for rental equipment, new purchased equipment, and used purchased equipment.

(2) The carrier adjusts the amount determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the local payment amounts for years after 1990.* For each year subsequent to 1990, the local payment amounts of the preceding year are increased or decreased by the covered item update. For 1991 and 1992, the covered item update is reduced by 1 percentage point.

(e) *Calculating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedule amounts are equal to the national limited payment amount.

(f) *Calculating the national limited payment amount.* The national limited payment amount is computed as follows:

(1) The 1991 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(2) The 1992 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

(iii) The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

(3) For 1993, the national limited payment amount is equal to one of the following:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts.

(ii) 100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts.

(iii) 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(4) For 1994 and subsequent years, the national limited payment amount is equal to one of the following:

(i) If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.

(ii) If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.

(iii) If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.

(g) *Payment for surgical dressings.* For monthly dressings furnished after December 31, 1993, the national limited payment amount is computed based on local payment amounts using average reasonable charges for the 12-month pe-

riod ending December 31, 1992, increased by the covered item updates for 1993 and 1994.

[57 FR 57689, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§ 414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* Items requiring frequent and substantial servicing in order to avoid risk to the beneficiary's health are the following:

(1) Ventilators (except those that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices).

(2) Continuous and intermittent positive pressure breathing machines.

(3) Continuous passive motion machines.

(4) Other items specified in CMS program instructions.

(5) Other items identified by the carrier.

(b) *Payment rule.* Rental payments for items requiring frequent and substantial servicing are made on a monthly basis, and continue until medical necessity ends.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for items requiring frequent and substantial servicing is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for rental of items requiring frequent and substantial servicing that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier adjusts the amounts determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedules are determined using the methodology contained in paragraphs (d), (e), and (f) of § 414.220.

(e) *Transition to other payment classes.* For purposes of calculating the 15-month rental period, beginning January 1, 1994, if an item has been paid for under the frequent and substantial servicing class and is subsequently paid for under another payment class, the

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rental period begins with the first month of continuous rental, even if that period began before January 1, 1994. For example, if the rental period began on July 1, 1993, the carrier must use this date as beginning the first month of rental. Likewise, for purposes of calculating the 10-month purchase option, the rental period begins with the first month of continuous rental without regard to when that period started. For example, if the rental period began in August 1993, the 10-month purchase option must be offered to the beneficiary in May 1994, the tenth month of continuous rental.

[57 FR 57690, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§ 414.224 Customized items.

(a) *Criteria for a customized item.* To be considered a customized item for payment purposes under paragraph (b) of this section, a covered item (including a wheelchair) must be uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

(b) *Payment rule.* Payment is made on a lump sum basis for the purchase of a customized item based on the carrier's individual consideration and judgment of a reasonable payment amount for each customized item. The carrier's individual consideration takes into account written documentation on the costs of the item including at least the cost of labor and materials used in customizing an item.

[56 FR 65998, Dec. 20, 1991, as amended at 58 FR 34919, June 30, 1993]

§ 414.226 Oxygen and oxygen equipment.

(a) *Payment rules.* (1) Payment for rental of oxygen equipment and purchase of oxygen contents is made based on a monthly fee schedule amount.

(2) Monthly fee schedule payments continue until medical necessity ends.

(b) *Monthly fee schedule amount.* (1) Monthly fee schedule amounts are separately calculated for the following items:

(i) Stationary oxygen equipment and oxygen contents (stationary and portable oxygen contents).

(ii) Portable oxygen equipment only.

(iii) Stationary and portable oxygen contents only.

(iv) Portable oxygen contents only.

(2) For 1989 and 1990, the monthly fee schedule amounts are the local payment amounts determined as follows:

(i) The carrier determines the base local average monthly payment rate equal to the total reasonable charges for the item for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving the item for the same period. In determining the local average monthly payment rate, the following limitations apply:

(A) Purchase charges for oxygen systems are not included as items classified under paragraph (b)(1)(i) of this section.

(B) Purchase charges for portable equipment are not included as items classified under paragraph (b)(1)(ii) of this section.

(ii) The carrier determines the local monthly payment amount equal to 0.95 times the base local average monthly payment amount adjusted by the change in the CPI-U for the six-month period ending December 1987.

(3) For years after 1990, the fee schedule amounts are determined using the methodology contained in § 414.220 (d), (e), and (f).

(c) *Application of monthly fee schedule amounts.* (1) The fee schedule amount for items described in paragraph (b)(1)(i) of this section is paid when the beneficiary rents a stationary oxygen system.

(2) Subject to the limitation set forth in paragraph (d)(2) of this section, the fee schedule amount for items described in paragraph (b)(1)(ii) of this section is paid when the beneficiary rents a portable oxygen system.

(3) The fee schedule amount for items described in paragraph (b)(1)(iii) of this section is paid when the beneficiary owns a stationary gaseous or liquid oxygen system.

(4) The fee schedule amount for items described in paragraph (b)(1)(iv) of this section is paid when the beneficiary owns or rents a portable gaseous or

portable liquid oxygen system and uses either a stationary oxygen concentrator or no stationary oxygen system.

(d) *Volume adjustments*: (1) The fee schedule amount for an item described in paragraph (b)(1)(i) of this section is adjusted as follows:

(i) If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the fee schedule amount is increased by 50 percent, subject to the limit in paragraph (d)(2) of this section.

(ii) If the attending physician prescribes an oxygen flow rate of less than one liter per minute, the fee schedule amount is decreased by 50 percent.

(2) If portable oxygen equipment is used and the prescribed oxygen flow rate exceeds four liters per minute, the total fee schedule amount recognized for payment is limited to the higher of—

(i) The sum of the monthly fee schedule amount for the items described in paragraphs (b)(1)(i) and (ii) of this section; or

(ii) The adjusted fee schedule amount described in paragraph (d)(1)(i) of this section.

(3) In establishing the volume adjustment for those beneficiaries whose physicians prescribe varying flow rates, the following rules apply:

(i) If the prescribed flow rate is different for stationary oxygen equipment than for portable oxygen equipment, the flow rate for the stationary equipment is used.

(ii) If the prescribed flow rate is different for the patient at rest than for the patient at exercise, the flow rate for the patient at rest is used.

(iii) If the prescribed flow rate is different for nighttime use and daytime use, the average of the two flow rates is used.

[57 FR 57690, Dec. 7, 1992]

§414.228 Prosthetic and orthotic devices.

(a) *Payment rule*. Payment is made on a lump-sum basis for prosthetic and orthotic devices subject to this subpart.

(b) *Fee schedule amounts*. The fee schedule amount for prosthetic and orthotic devices is determined as follows:

(1) The carrier determines a base local purchase price equal to the average reasonable charge for items purchased during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier determines a local purchase price equal to the following:

(i) For 1989 and 1990, the base local purchase price is adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(ii) For 1991 through 1993, the local purchase price for the preceding year is adjusted by the applicable percentage increase for the year. The applicable percentage increase is equal to 0 percent for 1991. For 1992 and 1993, the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(iii) For 1994 and 1995, the applicable percentage increase is 0 percent.

(iv) For all subsequent years the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(3) CMS determines the regional purchase price equal to the following:

(i) For 1992, the average (weighted by the relative volume of all claims among carriers) of the local purchase prices for the carriers in the region.

(ii) For 1993 and subsequent years, the regional purchase price for the preceding year adjusted by the applicable percentage increase for the year.

(4) CMS determines a purchase price equal to the following:

(i) For 1989, 1990 and 1991, 100 percent of the local purchase price.

(ii) For 1992, 75 percent of the local purchase price plus 25 percent of the regional purchase price.

(iii) For 1993, 50 percent of the local purchase price plus 50 percent of the regional purchase price.

(iv) For 1994 and subsequent years, 100 percent of the regional purchase price.

(5) For 1992 and subsequent years, CMS determines a national average purchase price equal to the unweighted average of the purchase prices determined under paragraph (b)(4) of this section for all carriers.

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(6) CMS determines the fee schedule amount equal to 100 percent of the purchase price determined under paragraph (b)(4) of this section, subject to the following limitations:

(i) For 1992, the amount cannot be greater than 125 percent nor less than 85 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(ii) For 1993 and subsequent years, the amount cannot be greater than 120 percent of the national average nor less than 90 percent of the national average purchase price determined under paragraph (b)(5) of this section.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

§ 414.229 Other durable medical equipment—capped rental items.

(a) *General payment rule.* Subject to the limitation set forth in paragraph (b) of this section, payment is made on a rental or purchase option basis for other durable medical equipment that is not subject to the payment provisions set forth in §§ 414.220 through 414.228.

(b) *Fee schedule amounts for rental.* (1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under § 405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991 and subsequent years, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 7.5 percent of the purchase price for each of the remaining months.

(c) *Determination of purchase price.* The purchase price of other covered durable medical equipment is determined as follows:

(1) For 1989 and 1990. (i) The carrier determines a base local purchase price amount equal to the average of the purchase prices submitted on an assignment-related basis of new items supplied during the 6-month period ending December 1986.

(ii) The purchase price is equal to the base local purchase price adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991. (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by the percentage by which the average of the reasonable charges for claims paid for all other items described in § 414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988.

(ii) The purchase price for 1991 is the national limited payment amount as determined using the methodology contained in § 414.220(f).

(3) For years after 1991. The purchase price is determined using the methodology contained in paragraphs (d) through (f) of § 414.220.

(d) *Purchase option.* Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses the purchase option. The purchase fee is the amount established in § 414.229(c).

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month from the date the supplier makes the offer to accept the purchase option.

(i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental

payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in §414.230.

(ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) *Payment for maintenance and servicing.* (1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made only for equipment that continues to be used after 15 months of rental payments have been made and is limited to the following:

(i) For the first 6-month period, no payments are to be made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period.

(3) Payment for maintenance and servicing DME purchased in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, is made on the basis of reasonable and necessary charges.

(f) *Transition to the fee schedules.* For purposes of computing the 10-month or 15-month period of continuous use for other durable medical equipment, as described in §414.230, the carrier counts the first month that the beneficiary continuously rented the equipment without regard to whether that month occurred before January 1, 1989 or after. If a beneficiary's 15-month rental period ends prior to January 1, 1989, no further purchase or rental payments are to be made except for maintenance and servicing of equipment as described in paragraph (e) of this section.

(g) *Replacement of equipment.* If the item of equipment has been in continuous use by the patient on either a rental or purchase basis for the equipment's useful lifetime, or if the carrier determines that the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement equipment, payment is made on a rental or purchase basis in accordance with paragraph (a) of this section or on a lump-sum purchase basis if a purchase agreement had been entered into in accordance with paragraph (d) of this section.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

§414.230 Determining a period of continuous use.

(a) *Scope.* This section sets forth the rules that apply in determining a period of continuous use for rental of durable medical equipment.

(b) *Continuous use.* A period of continuous use begins with the first month of medical need and lasts until a beneficiary's medical need for a particular item of durable medical equipment ends.

(c) *Temporary interruption.* (1) A period of continuous use allows for temporary interruptions in the use of equipment.

(2) An interruption of not longer than 60 consecutive days plus the days remaining in the rental month in which use ceases is temporary, regardless of the reason for the interruption.

(3) Unless there is a break in medical necessity that lasts longer than 60 consecutive days plus the days remaining in the rental month in which use ceases, medical necessity is presumed to continue.

(d) *Criteria for a new rental period.* If an interruption in the use of equipment

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continues for more than 60 consecutive days plus the days remaining in the rental month in which use ceases, a new rental period begins if the supplier submits all of the following information—

(1) A new prescription.
(2) New medical necessity documentation.

(3) A statement describing the reason for the interruption and demonstrating that medical necessity in the prior episode ended.

(e) *Beneficiary moves.* A permanent or temporary move made by a beneficiary does not constitute an interruption in the period of continuous use.

(f) *New equipment.* If a beneficiary changes equipment or requires additional equipment based on a physician's prescription, and the new or additional equipment is found to be necessary, a new period of continuous use begins for the new or additional equipment. A new period of continuous use does not begin for base equipment that is modified by an addition.

(g) *New supplier.* If a beneficiary changes suppliers, a new period of continuous use does not begin.

[56 FR 50823, Oct. 9, 1991, as amended at 57 FR 57111, Dec. 3, 1992]

§ 414.232 Special payment rules for transcutaneous electrical nerve stimulators (TENS).

(a) *General payment rule.* Except as provided in paragraph (b) of this section, payment for TENS is made on a purchase basis with the purchase price determined using the methodology for purchase of inexpensive or routinely purchased items as described in § 414.220. The payment amount for TENS computed under § 414.220(c)(2) is reduced according to the following formula:

(1) Effective April 1, 1990—the original payment amount is reduced by 15 percent.

(2) Effective January 1, 1991—the reduced payment amount in paragraph (a)(1) is reduced by 15 percent.

(3) Effective January 1, 1994—the reduced payment amount in paragraph (a)(1) is reduced by 45 percent.

(b) *Exception.* In order to permit an attending physician time to determine whether the purchase of the TENS is

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medically appropriate for a particular patient, two months of rental payments may be made in addition to the purchase price. The rental payments are equal to 10 percent of the purchase price.

[57 FR 57692, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§ 414.300 Scope of subpart.

This subpart sets forth criteria and procedures for payment of the following services furnished to ESRD patients:

(a) Physician services related to renal dialysis.

(b) Physician services related to renal transplantation.

(c) Home dialysis equipment, supplies, and support services.

(d) Epoetin (EPO) furnished by a supplier of home dialysis equipment and supplies to a home dialysis patient for use in the home.

[55 FR 23441, June 8, 1990, as amended at 56 FR 43710, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994]

§ 414.310 Determination of reasonable charges for physician services furnished to renal dialysis patients.

(a) *Principle.* Physician services furnished to renal dialysis patients are subject to payment if the services are otherwise covered by the Medicare program and if they are considered reasonable and medically necessary in accordance with section 1862(a)(1)(A) of the Act.

(b) *Scope and applicability*—(1) *Scope.* This section pertains to physician services furnished to the following patients:

(i) Outpatient maintenance dialysis patients who dialyze—

(A) In an independent or hospital-based ESRD facility, or

(B) At home.

(ii) Hospital inpatients for which the physician elects to continue payment under the monthly capitation payment (MCP) method described in § 414.314.

(2) *Applicability.* These provisions apply to routine professional services